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TITLE: Efficacy of Calcium and Vitamin D Supplementation for the
Prevention of Stress Fractures in Female Naval Recruits

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13. ABSTRACT (Maximum 200 Words) <p>The goal of this project is to determine if calcium and vitamin D intervention can reduce the incidence of stress fracture by at least 50% in female Naval recruits during basic training. We will recruit 5200 recruits who will be randomly assigned to an intervention group given calcium 2000 mg and vitamin D 800 I.U. per day or a control placebo group. The recruit intervention and stress fracture monitoring will continue through 8 weeks of basic training. Positive findings from this study would provide support for the Navy to adopt an easy, low cost method of further decreasing incidence of stress fractures.</p> <p>In May 2004, the DOD approved our protocol amendment to perform peripheral quantitative computed tomography (pQCT) measurements on a subset of recruits. The purpose of the substudy is to examine potential mechanisms for increasing bone adaptation to intense mechanical loading. We are performing the pQCT measurements. To date we have enrolled 4454 female recruits into the study, and 3518 have completed. We are retaining about 79% of enrolled participants. We have no findings to date.</p>				
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Annual Report for Period of October 1, 2003- September 30, 2004**Project title: Efficacy of calcium and vitamin D supplementation for the prevention of stress fractures in female Naval recruits****Introduction**

Stress fractures during military basic training remain a major concern despite training modifications that have decreased stress fracture incidence. Stress fractures are especially prominent in women. These injuries result in loss of manpower and high medical expense, occasionally incurring service-related disability. Supplementing female recruits with calcium and vitamin D may supply nutrients needed to meet training demands and thereby significantly reduce risk of fracture. Inadequate calcium and vitamin D intake may limit bone adaptation since recruits under 30 years of age have not achieved peak bone mass, training stimulates bone formation and micro-fracture repair, calcium intakes are normally low, and substantial dermal calcium losses occur during training. The goal of this project is to determine if calcium and vitamin D intervention can reduce the incidence of stress fracture by at least 50% in female Naval recruits during basic training. The secondary goal is to examine the potential mechanisms for increasing bone adaptation to intense mechanical loading. We will recruit 5200 recruits who will be randomly assigned to an intervention group given calcium 2000 mg and vitamin D 800 I.U. per day or a control placebo group. The recruit intervention and stress fracture monitoring will continue through 8 weeks of basic training. Positive findings from this study would provide support for the Navy to adopt an easy, low cost method of further decreasing incidence of stress fractures.

Body

Research accomplishments associated with each task outlined in the approved Statement of Work are outlined in Table 1. After receiving notification of funding, we worked with the DOD regulatory persons and our institutional review board as quickly as possible to obtain approval for starting the study. We did not receive final approval from the DOD until April 2004. We started recruitment one month later. We were actively recruiting until September 26, 2002 when we were notified by the Great Lakes IRB that we were to stop recruitment and put the study on hold. We understand that all active clinical projects were stopped at the Great Lakes at that time. We were allowed to complete follow up of enrolled subjects.

Table 1. Research Accomplishments Associated with Tasks in the Statement of Work

	Original	Actual/Projected	Explanation of discrepancies
Planning and set up	7/01-12/01	9/01-5/02	Although the project was funded 9/01, the DOD did not approve us to start until 4/02. We started one month after approval.
Enrollment, intervention and data collection	1/01 - 12/03	5/02 - 8/05	About 4.5 months after startup, enrollment was put on hold by the Great Lakes IRB for about 10 months.
Data clean up and analysis	1/04-6/04	8/05 - 9/05	Delayed as described above

The project was reapproved by the Great Lakes IRB on August 7, 2003, and we restarted recruitment on September 18, 2003. We were provided money from the DOD to purchase a Stratec peripheral quantitative computed tomography (pQCT) device. We submitted the protocol amendment for the pQCT to the Great Lakes IRB in September 2003 and received approval in January 2004. We immediately requested that the DOD approve the protocol amendment, but we did not receive that approval until May 2004. We have started the pQCT substudy. On July 22, 2004, we were granted an extension of our contract through September 2005.

To date we have enrolled 4454 study participants in the overall study. We have completed 3518 study participants for a retention rate of 79%.

The mean age of the study participants is 20.2 (± 2.7) years. The ethnic/racial breakdown is as follows: American Indian/Alaskan 3.41%; Asian 4.16%; Black/non-Hispanic 17.94%; Hispanic or Latino 12.66%; White/non-Hispanic 58.87% and other 2.95%.

Key Research Accomplishments

- Implementation of a project that does not interfere with the flow of Naval basic training
- Prompt restart of the project after approval, including hiring and training of new study personnel
- Retention of 79% of enrolled subjects
- Implementation of pQCT substudy
- Completion of 3518 study participants

Reportable Outcomes

No reportable outcomes at this time.

Conclusions

We are drawing no conclusions at this time since we have not completed the study.

References

None

Appendices

None

Revisions in response to reviewer comments:

Response Reviewers:

- 1) Progress of pQCT recruitment. We are completing the precision sub-study. We were delayed with start-up of the pQCT recruitment because of equipment problems. After we started the precision sub-study, the device failed. We did not have money in the budget for the \$10,000 repair. We asked for additional funds in November 2004 and received approval, although we have not yet received the money. We have had the pQCT repaired and have purchased a service contract. Enlistment at the Great Lakes is very low right now, and we plan to start the pQCT in full force at the end of May 2005. We plan to make measurements of the tibia at three sites: 3 sites 4%, 14%, and 38% to include a scout scan and 2 scans per site.
- 2) There have been 249 stress fractures identified since the beginning of study.
- 3) The person adjudicating the fractures at Creighton is Robert R. Recker, M.D., Director of the Osteoporosis Research Center.
- 4) There have been no adverse events reported since the last annual report.